Developing a case for an international extension of RICA

Marcus Flather, Manuel Montero Perez-Barquero, Luis Manzano Espinosa

Norwich Medical School, University of East Anglia UK
IMIBIC Hospital Reina Sofia and Univ Cordoba, Cordoba
Hospital Ramon y Cajal Madrid and University of Alcala

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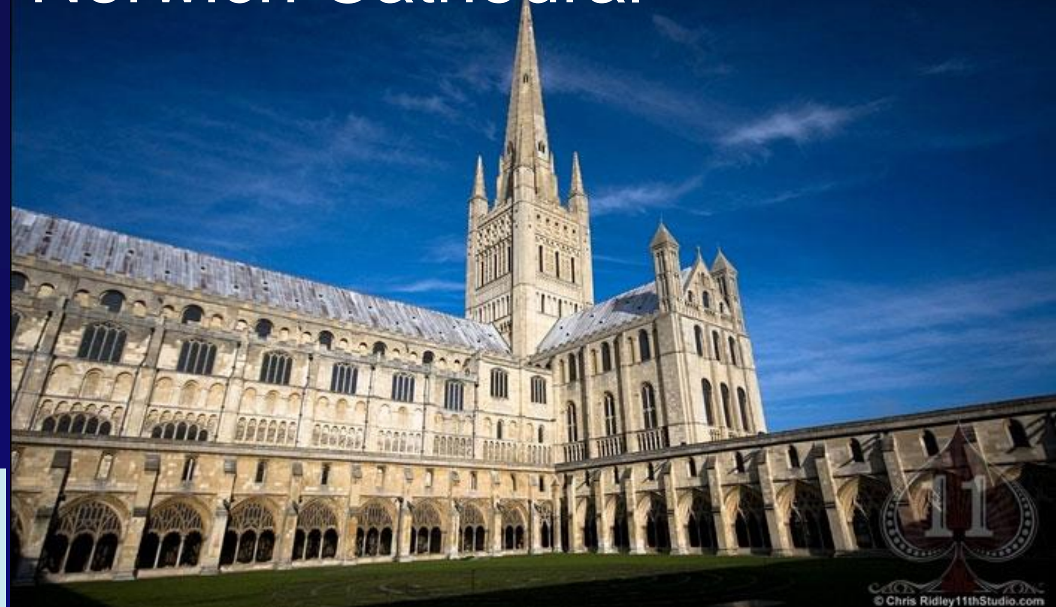
m.flather@uea.ac.uk

Where is Norwich?

University of East Anglia And Norfolk and Norwich University Hospital

Norwich Cathedral



Sainsbury Centre for Visual Arts

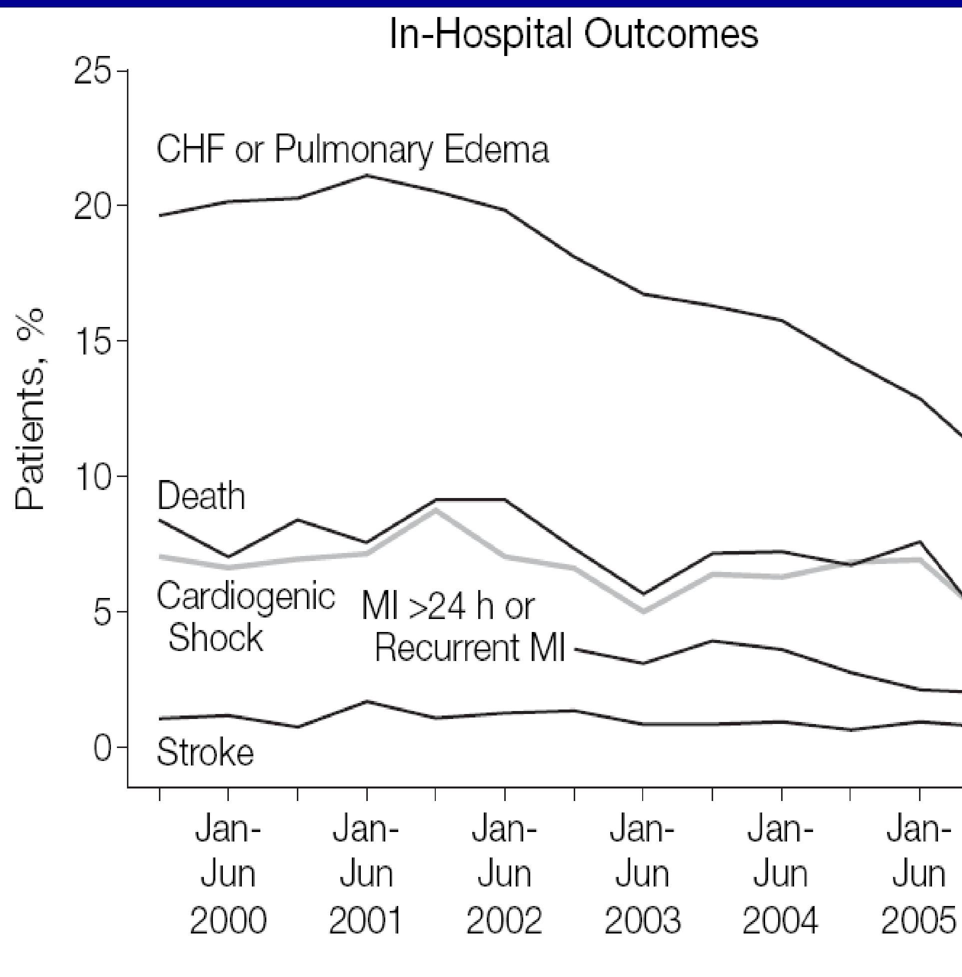
Importance of registries

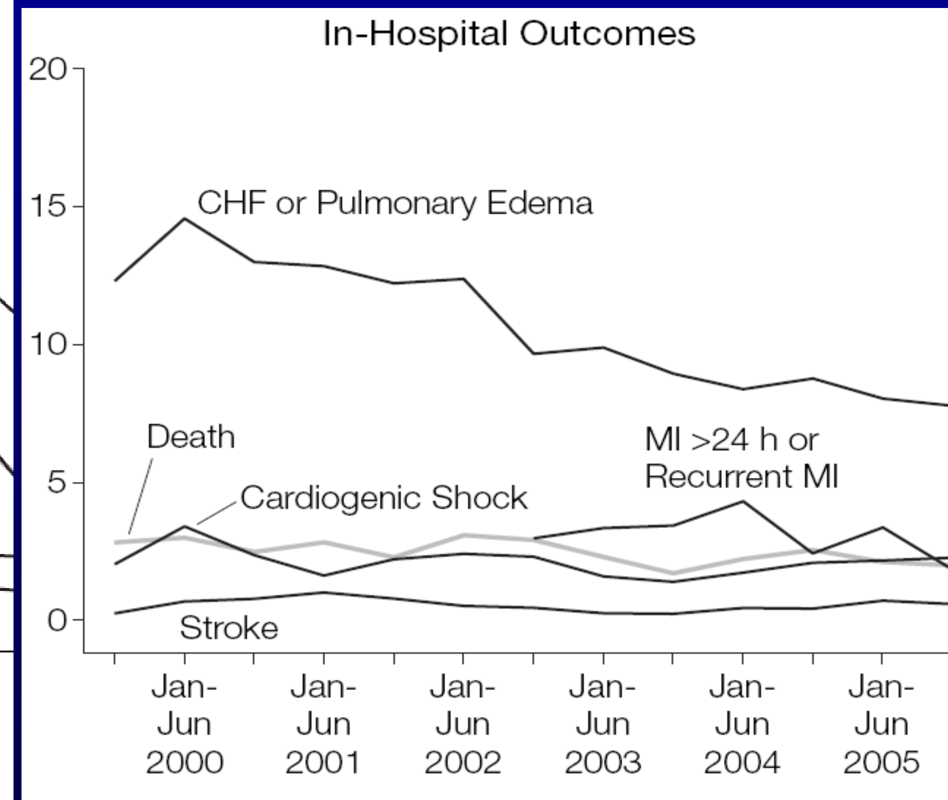
- Information on patient characteristics, treatments and outcomes in “real world” settings
- Encourage health providers to collaborate
- Data on costs and health economic aspects
- Monitor changing trends in demographics, treatments and outcomes
- Tool for quality improvement and assurance
- Develop risk models to target treatments
- Inform health policy and public education

Trends in death, heart failure and other complications after admission for ACS n= 44372

STEMI/ LBBB

Non ST elevation (NSTEMI/ UA)



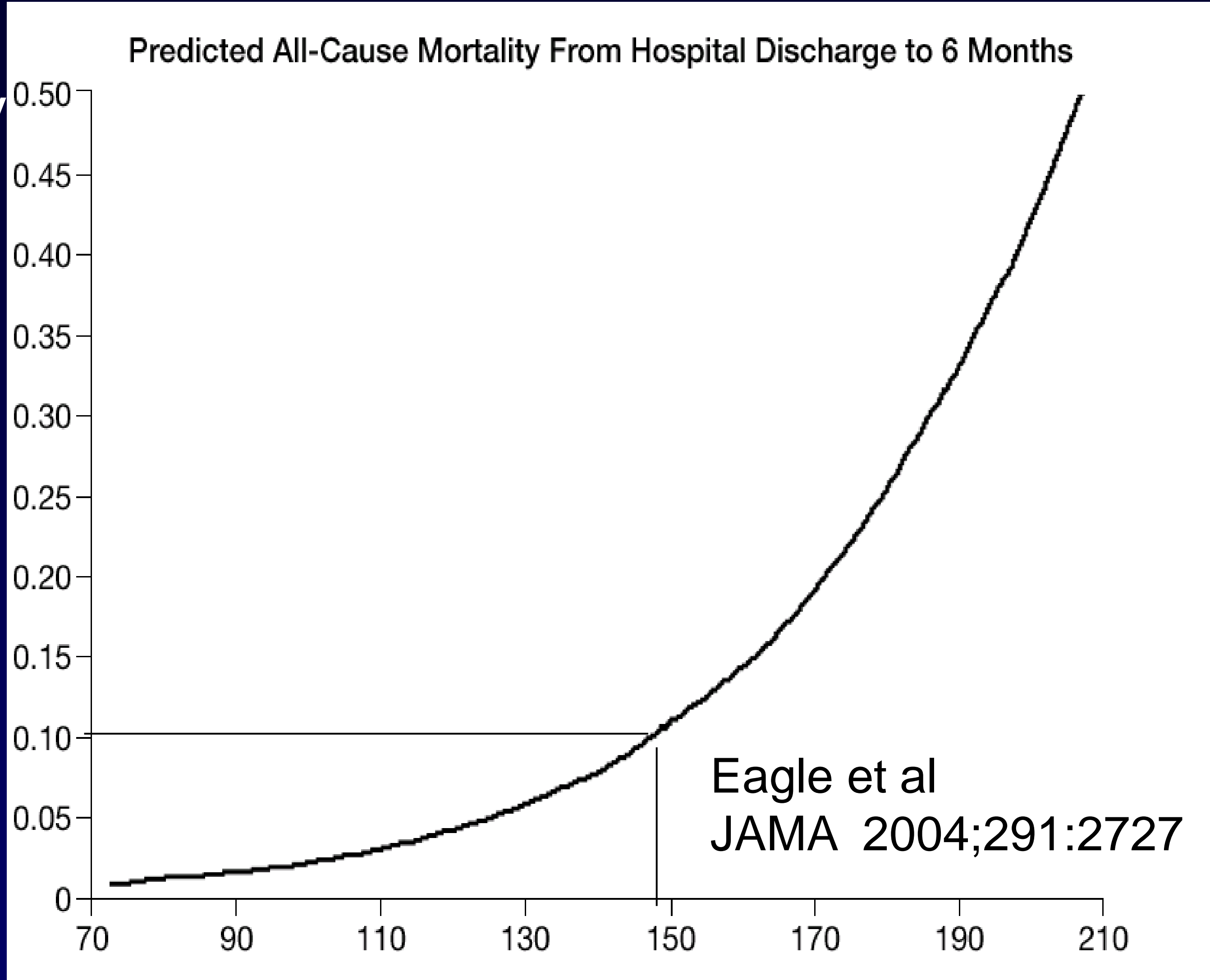


Year of enrolment

Fox et al *JAMA. 2007;297:1892-1900*

GRACE Risk Score Prediction Nomogram

Probability of death



Numerical risk score

GRACE Risk score now incorporated into European Guidelines

RICA Registry overview

- Observational study, set up in 2008
- 50 hospitals rising to 70 hospitals, 4200 patients
- Enrolling heart failure admissions aged >50 years, ESC criteria of HF, discharged alive
- Data entered on web based case report form, central checking and analysis
- Sponsored and part funded by SEMI with funding from industry and other sources
- Academically led
- Aim is to understand HF demographics and treatments, prognosis and improve care

RICA assessment of impact

- Collaborating centres include a range of health care institutions – increases generalisability, information exchange and quality improvement
- ~20 publications at National/ European level
- Insights into patient characteristics and prognosis
- Development of a risk model
- Practice changes: introducing dedicated HF services e.g. UMIPIC, increase in evidence based treatments e.g. anticoagulation for AF

Insights from RICA: Mean blood pressure and prognosis (n=581)

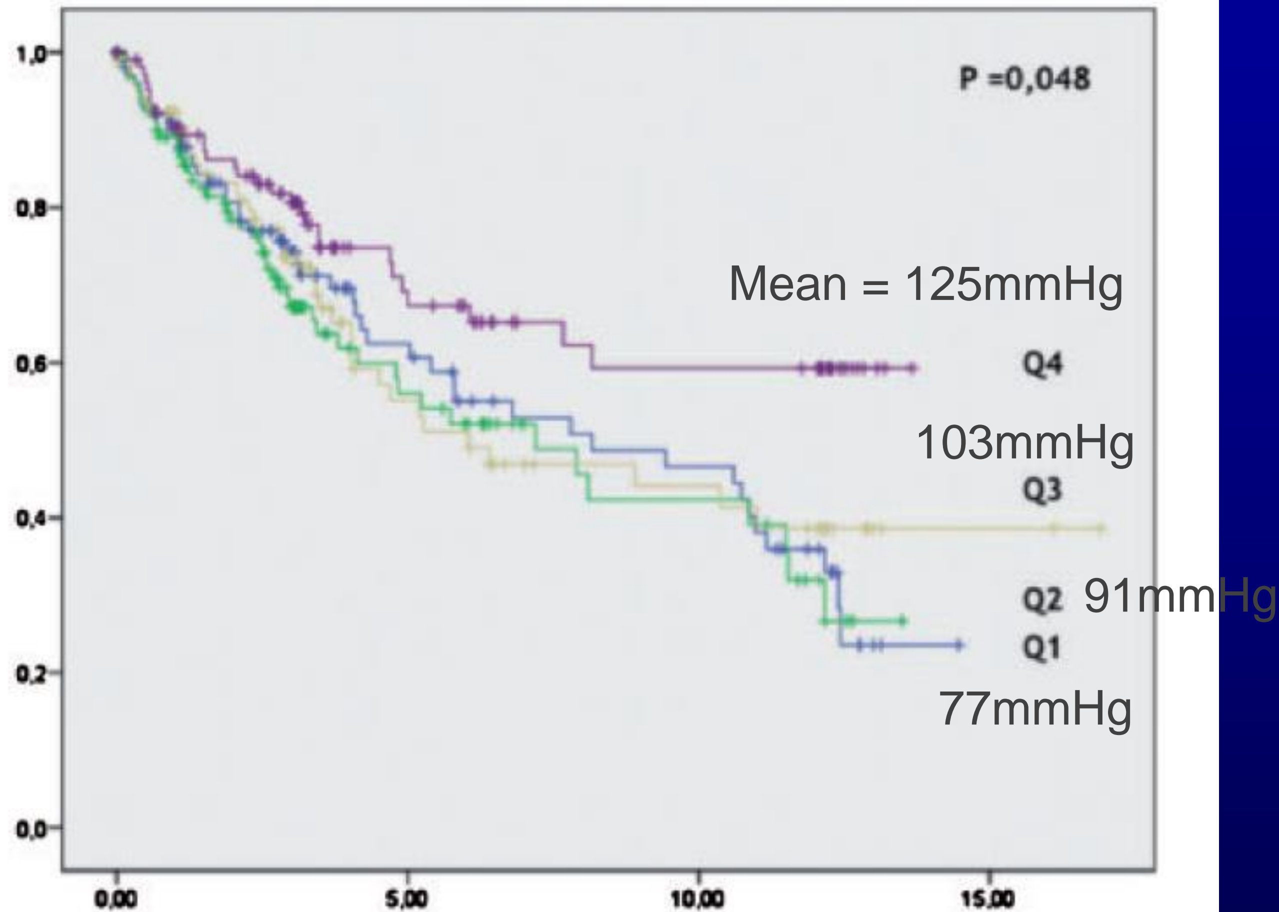
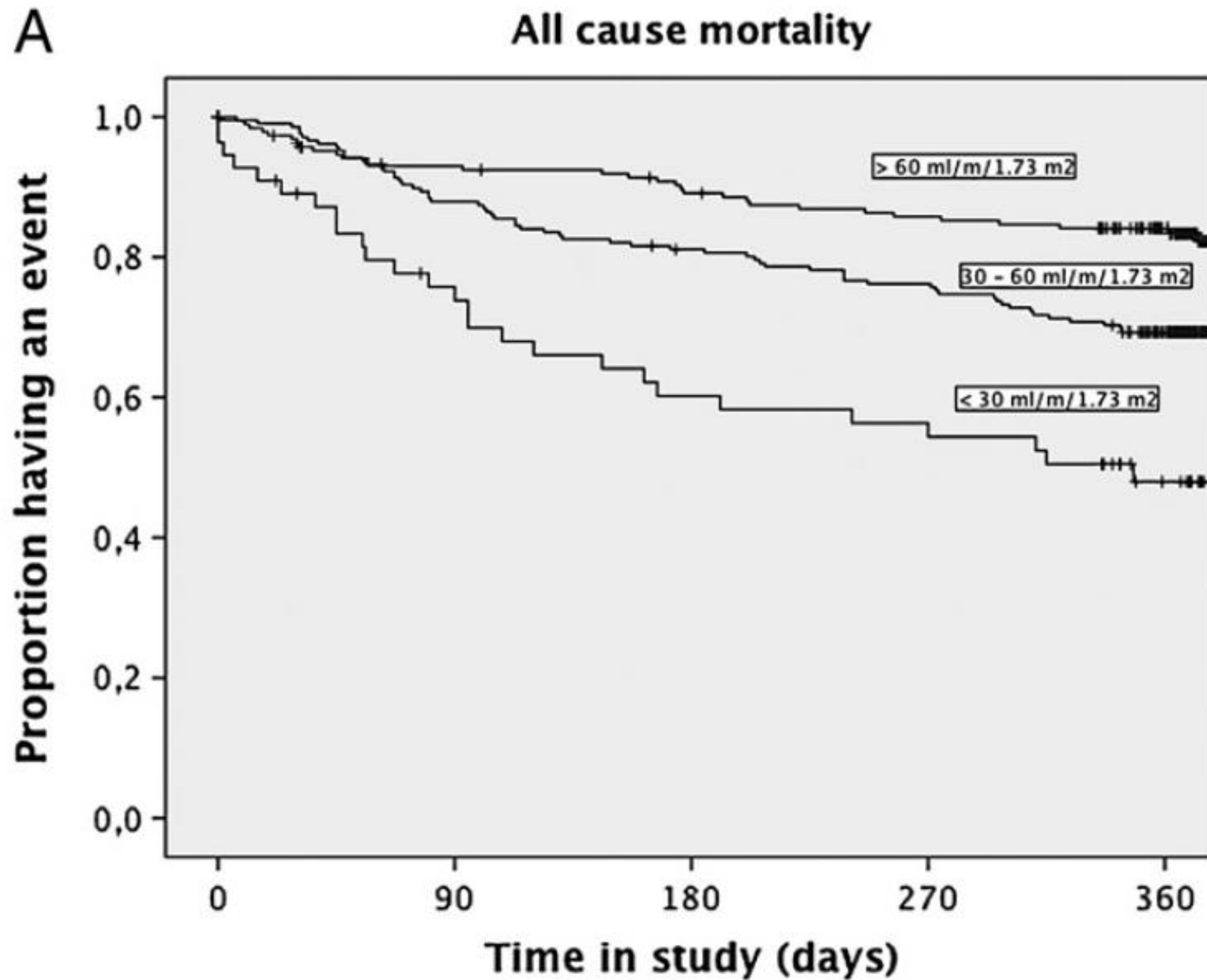


Figure 1. Months to first event (readmission or death).

Pérez-Calvo JI et al QJM. 2011 Apr;104(4):325-33.

Insights from RICA: Renal function and prognosis



eGFR

>60ml/min/1.73m^2

30-60

<30

n = 455

Jesús Casado et al Eur J Intern Med. 2013 Oct;24(7):677-83.

RICA: Functional status and 3 month outcomes

Barthel index: patients' ability for feeding, grooming, bathing, toilet use, dressing, walking, transfers, climbing stairs, fecal incontinence and urinary incontinence score up 100 for full activities

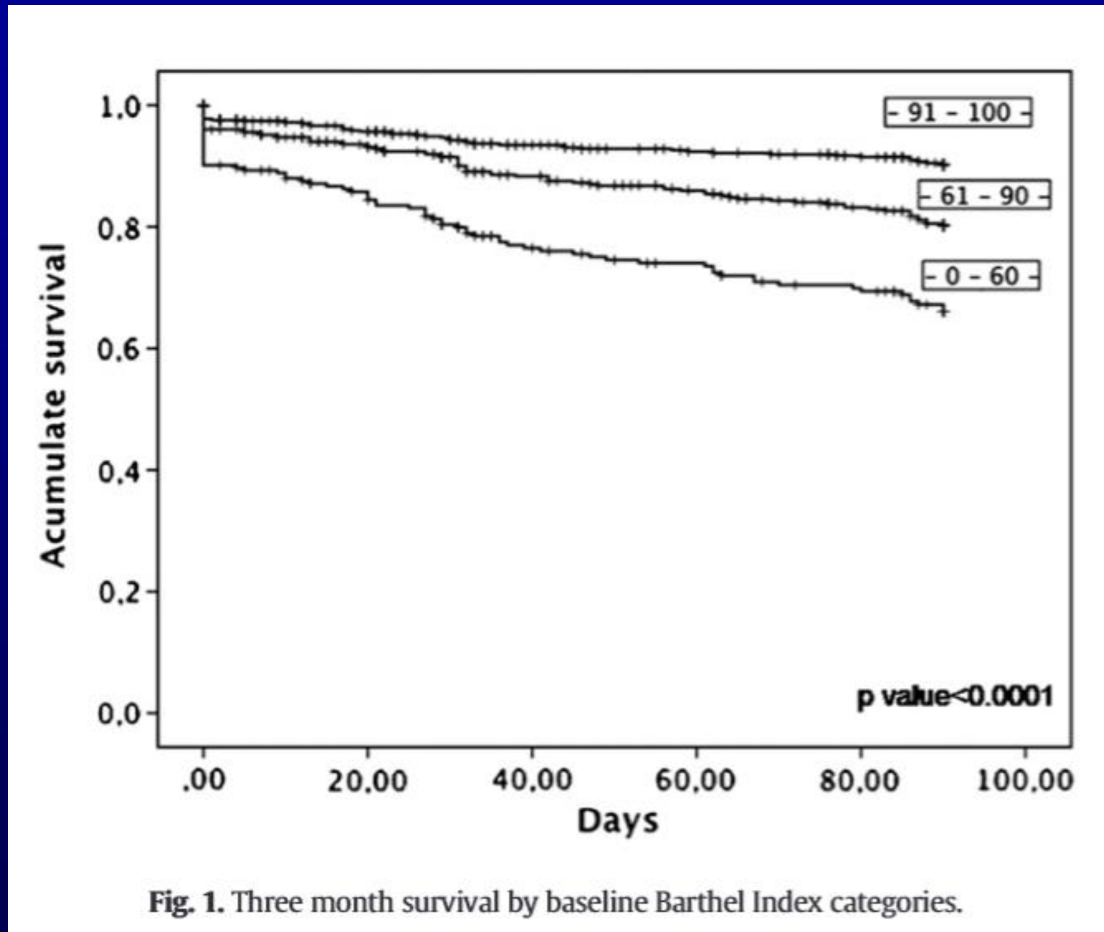
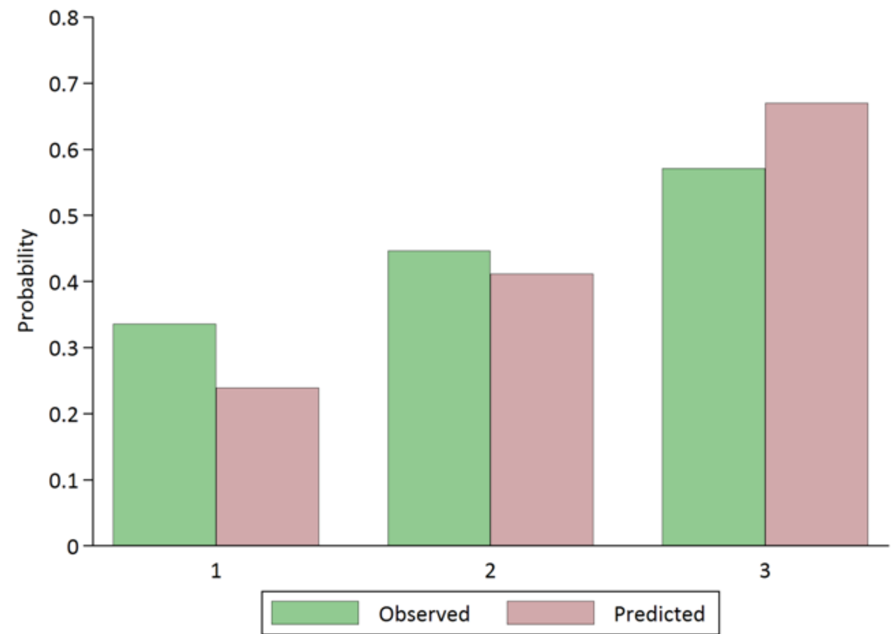


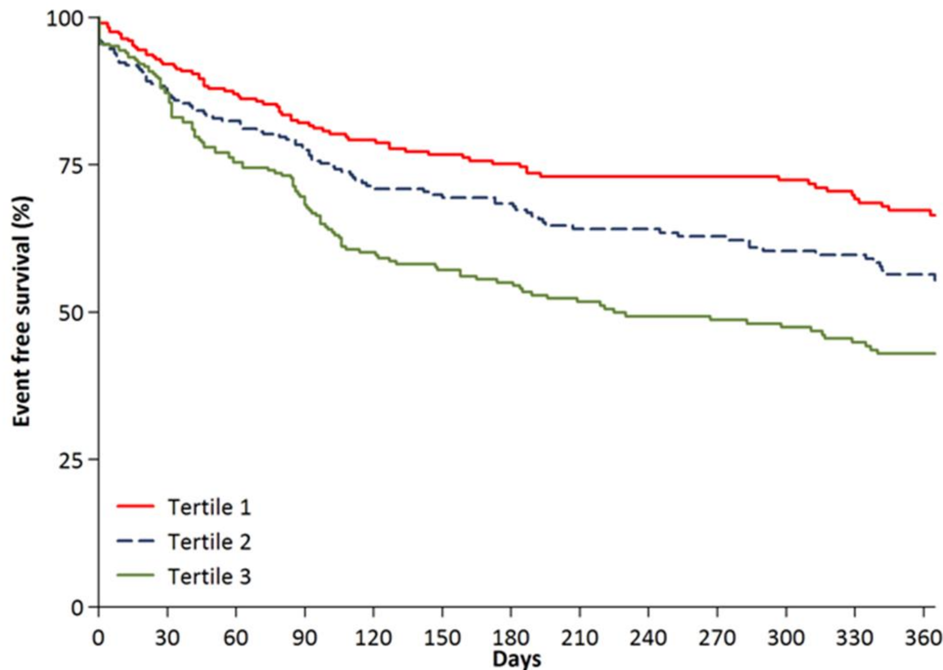
Fig. 1. Three month survival by baseline Barthel Index categories.

n = 1431

Francesc Formiga,et al International Journal of Cardiology Volume 172, Issue 1, 1 March 2014, Pages 127–131

Prediction of all cause mortality or CV hospitalisation in RICA using SENIORS risk model





p < 0.001, test long rank.

Montero, Manzano, Flather 2014 International Journal of Cardiology . 2015 Mar 1;182:449-53.

What are other HF registries doing?

- Get with the guidelines (US)
- ADHERE
- OPTIMIZE
- European Heart Failure Surveys
- UK National Heart Failure Survey
- These registries are providing insights on demographics, outcomes and treatment patterns but also focussing on quality of care
- Little work done is being done on health economic aspects and risk stratification

Why should RICA consider an international extension?

- Current model (coordination, data collection, analysis) is working well and is stable
- Extending to other countries increases impact of results with greater visibility
- Allows comparisons and generalisations across health systems
- International evaluation of quality of care
- Opportunity for quality improvement programmes
- Generate hypotheses for clinical trials

What would be needed for international extension?

- Selection of countries and collaborators
- Initially adding 3 countries may work: Northern Europe (e.g. UK), Eastern Europe (e.g. Poland) and in a non-EU country (e.g. Turkey)
- 5 centres per country to start would be reasonable
- Coordination capacity would need to expand
- Considerable amount of work to obtain approvals and set up centres
- Quality assurance of data
- Additional funds to support the extension

Quality of care improvement cycle

Quality improvement

Information on practice
(Audit and epidemiology)

Analysis and results

Risk
stratification
Models

Dissemination

Clinical trials
and
other evidence

Setting new standards
and guidelines

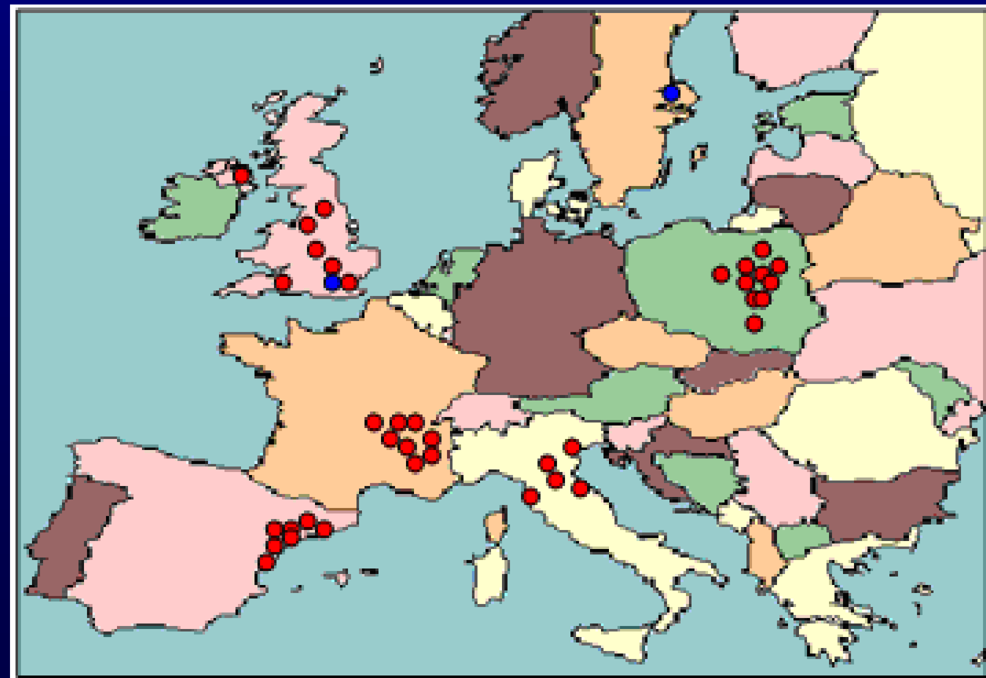
Changing behaviour
New policies

European Quality Improvement Programme for Acute Coronary Syndromes: *EQUIP-ACS*

- Quality improvement (QI) programme for non ST elevation acute coronary syndromes
- Research grant from GSK (Euros 600K)
- 38 hospitals in 5 countries
- Cluster randomised to QI or no QI programme
- 12 months recruitment
- 4400 patients enrolled

Flather et al Am Heart J. 2011 Oct;162(4):700-707.e1.

Clinical Trials & Evaluation Unit



EQUIP Study design- flow chart

PHASE 1: Centre selection and training

39 centres

PHASE 2: Run-in period *(~ 1 month)*

39 centres

Cluster Randomisation

PHASE 3: Baseline *(3.5 months)* 1481 patients

19 centres

19 centres

PHASE 4: QI Phase *(5 months)* 1722 patients

QI centres

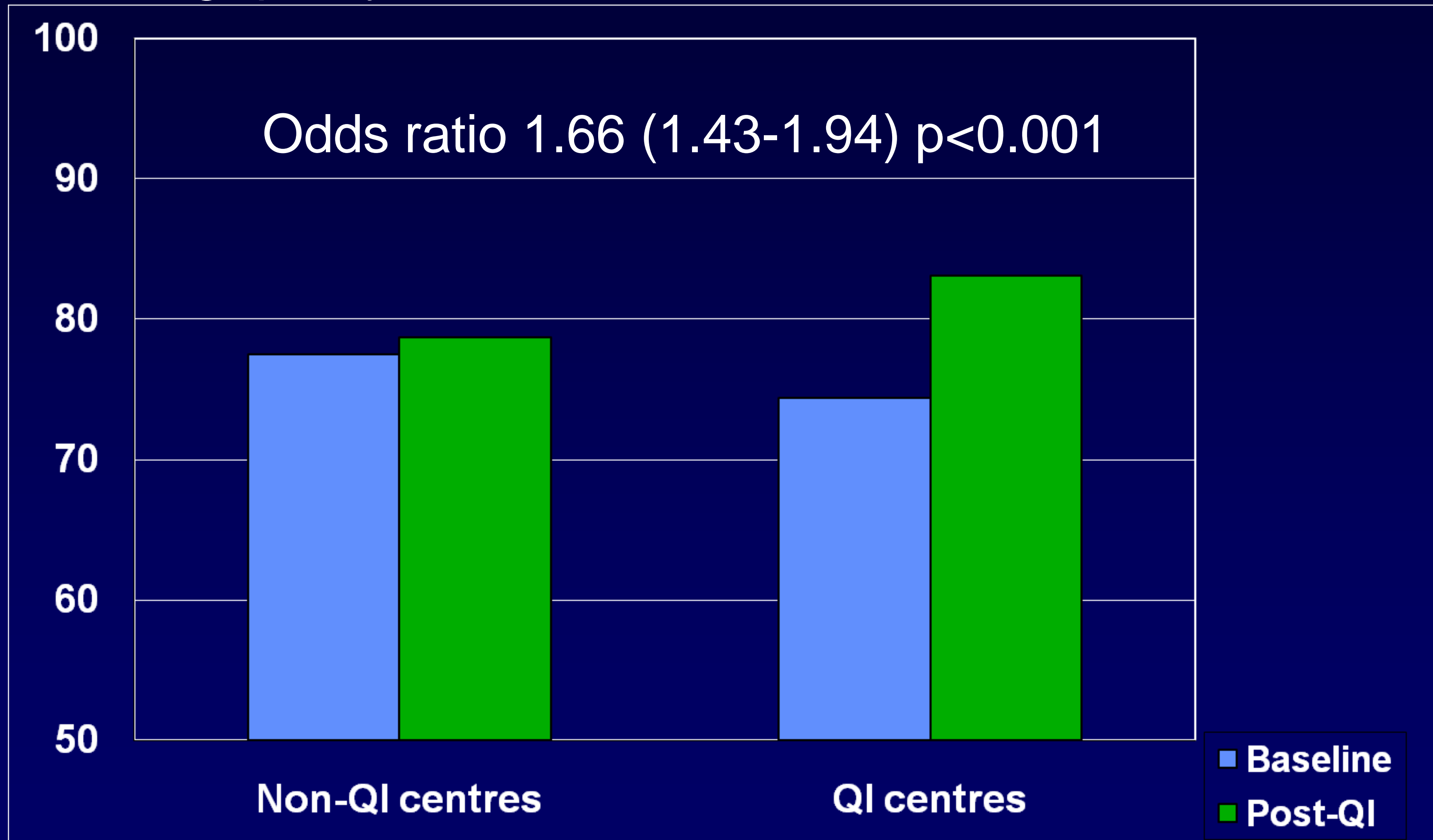
Non-QI centres

PHASE 5: Post-QI phase *(3 months)* *1237 patients*

Flather et al Trials 2010

EQUIP ACS: Primary outcome
(risk stratification, Cor angio, anticoagulant, statin, beta blocker, ACE-I, clopidogrel) ESC 2010

% achieving quality indicator



Flather et al Am Heart J. 2011 Oct;162(4):700-707.e1.

Funding options for an international registry

- Industry sources: if available these are reliable and proven to work: can fund large sections of activity
- European Union: complex processes chances of success low but could be better with industry partnerships
- Professional societies: e.g. EFIM, ESC, heart failure groups could provide endorsements and small amounts of funds
- National agencies, charities, health care providers should all be considered as partners/ part funders